REMARKS

Applicants respectfully request entry of the present amendment and reconsideration of the claims currently pending. Claims 15-16 and 18-24 are pending in the present application.

I. The Rejection of Claims 15-16, 18-24 Under the Enablement Standard of § 112, 1st Paragraph Must be Withdrawn. (5th Paragraph of the Office Action)

Although the Office Action states that the specification does not disclose the identity of the body fluid employed to produce the data disclosed at pages 7-16 of the specification, the body fluid that is the source of that data, and the method used to produce it, are clearly set forth in the specification. The specification states:

> The present invention uses a sample of amniotic fluid to generate a comprehensive metabolic profile to diagnose chromosomal abnormalities in the fetus. (p. 4, l. 19-20) ...
>
> For example, a procedure similar to one described by Shoemaker and Elliott can be used to screen a specimen of amniotic fluid from metabolites. (p. 4, l. 23-24) ...
>
> A specimen of amniotic fluid is first obtained. For example, amniotic fluid may be taken from around the fetus during pregnancy. The specimen then is analyzed by gas chromatograph/mass spectrophotometer (GC/MS).
>
> . . .
>
> The results of the GC/MS analysis are then used to generate the profile of the metabolites previously identified. The sample profile is compared with a control profile of metabolites that is representative of the normal levels of those metabolites. (p. 5, l. 3-8).

Under the section entitled "DETAILED DESCRIPTION OF THE INVENTION," the specification states:

> As previously discussed a procedure similar to the procedure described by Shoemaker and Elliott may be used to screen an amniotic fluid specimen for metabolites. An amniotic fluid specimen is obtained from the fetus to be evaluated. (p. 5, l. 18-20).

Under the heading "Example Profile Analysis" at page 7, the specification unequivocally states:

> "Using the aforementioned GC/MS procedure, a metabolic profile for a group of 23 Down Syndrome patients was generated." (p. 7, l. 24-p.8, l. 1).

Thus, it is beyond dispute that the specification discloses amniotic fluid as the body fluid employed to produce the data provided in the specification, expressly discloses the data allowing one to diagnose and identify Down Syndrome in a fetus by levels of metabolites in amniotic fluid, and expressly discloses the method in which differences in the quantities of a plurality of metabolites in amniotic fluid are employed in the diagnosis of Down Syndrome.

Because the Office Action acknowledges that the specification would be deemed enabling pursuant to § 112, 1st ¶ if the specification identified the bodily fluid employed in obtaining the data on pages 7-16, and as noted above, because the specification clearly identifies the fluid, Applicant submits that disclosure of the specification readily surpasses the quantity of information necessary to comply with the enablement requirement of § 112.

Applicant notes that the rejection of the pending claims under § 112, 1st ¶ pursuant to the enablement standard is repeatedly characterized by the Examiner as an issue of "predictability." Issues of predictability can become relevant when an applicant seeks to secure claims that are dramatically broader than the subject matter enabled by the specification. See The Incandescent Lamp Patent, 159 U.S. 465 (1895); O'Reilly v. Morse, 56 U.S. 62, 86 (1853); Amgen v. Chugai Pharmaceutical, 925 F.2d 1200 (Fed. Cir. 1991); United States Steel Corporation v. Phillips

Petroleum Company, 865. F.2d 1247 (Fed. Cir. 1989); and Application of Fisher, 427 F.2d 833, 16 USPQ 18 (CCPA 1970);. The concerns of claim over-breadth raised by these cases do not apply in the present case. The pending claims specify the use of amniotic fluid as the analyte, specify the analysis of quantity using GC/MS, and specify the analysis wherein a subset of metabolites is compared to control value for each analyte. Thus, the scope of the claims is perfectly in accord with the disclosure of the specification and considerations of unpredictability do not arise.

II. The Amended Claims are Sufficiently Definite to Satisfy the Requirements of § 112, 2nd ¶ to Particularly Point Out and Distinctly Claim the Subject Matter of the Invention. (Paragraph 7 of the Office Action).

The perceived lack of antecedent basis in reciting a quantity for the respective metabolite has been corrected in claim 15and the nature of the control profile is clarified to specify that it is "representative of normal levels of each metabolite."

The request for clarification regarding the comparison of the quantities in the subset of metabolites with the respective metabolites of the control profile in claims 15-16, 18-20, and 24 is clarified by amending claim 15 to specify that it is the quantity of a subset of metabolites that is compared with the respective metabolite of the control profile.

With respect to claims 21-23, claim 21 is amended to specify that the abnormal quantities of metabolites in a patient known to have Down Syndrome is measured in amniotic fluid. A similar clarification is made in claim 15.

CONCLUSION

Applicant notes the Examiner's conclusion regarding the absence of prior art disclosing the claimed method, and submits that the foregoing amendments and comments render the application in condition for allowance and respectfully requests such action accordingly.

By entry of this Amendment, Applicant respectfully submits that all of the Examiner's rejections have been overcome. Additionally, the Examiner is invited to telephone the undersigned representative if the Examiner believes that a telephonic interview would advance this case to allowance.

Respectfully submitted,

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In the Claims:

15. A method of identifying a presence of Down Syndrome in a fetus, comprising:

obtaining an amniotic fluid specimen by placing a syringe having a needle into a uterus and withdrawing the amniotic fluid specimen via the needle,

identifying a quantity for each metabolite that is present in the amniotic fluid specimen using a gas chromatograph/mass spectrometer,

compiling a patient profile, wherein the patient profile lists each metabolite and the quantity for each respective metabolite,

comparing the patient profile with a control profile representative of normal levels of each metabolite, wherein the control profile lists a [the] quantity for each respective metabolite of the patient profile that is present in amniotic fluid of persons with Down Syndrome, by comparing the quantity of each metabolite of the patient profile with the quantity for that respective metabolite of the control profile, and

identifying the presence of Down Syndrome in the fetus when a quantity of a subset of metabolites of the patient profile has a different quantity than each respective metabolite of the control profile.

21. A method of identifying a presence of Down Syndrome in a fetus, comprising:

obtaining an amniotic fluid specimen by placing a needle into a uterus and withdrawing the amniotic fluid specimen via the needle,

identifying a quantity for each metabolite that is present in the amniotic fluid specimen by analyzing the amniotic fluid specimen using a gas chromatograph/mass spectrometer,

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compiling a patient profile, wherein the patient profile lists each metabolite and the quantity for each respective metabolite present in the amniotic fluid specimen,

obtaining a control profile, wherein the control profile lists a quantity for each metabolite present in the amniotic fluid specimen for a population of patients without Down Syndrome.

identifying a plurality of abnormal quantities of metabolites of the patient profile by comparing the quantity of each metabolite of the patient profile with the quantity for that respective metabolite of the control profile, and

identifying the presence of Down Syndrome in the fetus when the plurality of abnormal quantities of metabolites of the patient profile corresponds to abnormal quantities of those metabolites in amniotic fluid of a patient known to have Down Syndrome.